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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/629,309   | 07/29/2003  | J. R. Patil          | U 014742-0          | 6603             |
| 140  | 7590        | 02/08/2005           | EXAMINER            |                  |
| LADAS & PARRY<br>26 WEST 61ST STREET<br>NEW YORK, NY 10023 |             |                      | KOSSON, ROSANNE     |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1651                |                  |

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/629,309

Applicant(s)

PATIL ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 7-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Mar. 11, 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/14/04, 8/6/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicants' election with traverse of Group I, claims 1-6, in the reply filed on December 27, 2004 is acknowledged.

Claims 7-19 (Group II) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP §818.03(a)). Therefore, the restriction requirement is maintained and has been made final.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although the genus of bioemulsifiers from *Acinetobacter* is discussed in the specification, there is no evidence that any representative species of such a large and varied genus was in the possession of the

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inventors at the time of filing. To satisfy the written description aspect of 35 U.S.C. 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. The specification does not disclose any representative species of any of the recited classes of possible bioemulsifiers, with or without identifying characteristics. Only the bioemulsifier produced by fermenting *Acinetobacter junii* SC14 (NCIM 5150) is disclosed.

Further, claim 1 is directed to a bioemulsifier comprising 50.5% protein, 43% polysaccharide and 3.8% lipid, where the components of the claimed product are not defined. Only the genus of each component, i.e., the general class of biomolecules in which the components may be categorized, is indicated. This claim language encompasses a multitude of possible proteins, polysaccharides and lipids, including proteins, polysaccharides and lipids neither contemplated nor disclosed by the specification as filed. Applicants have not provided any name, description or structure for the protein, polysaccharide or lipid, apart from disclosing that the protein has esterase activity. Applicants have also not provided any guidance for selecting or identifying proteins, polysaccharides or lipids that may be used in the claimed bioemulsifier. In view of the great extent of the claimed subject matter, combined with the fact that the specification as filed provides a description of a bioemulsifier containing

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protein, polysaccharide and lipid in a particular ratio and in which the protein is an esterase, it is clear that at the time of filing the application, Applicants possessed those only those compounds actually set forth in the specification. Therefore, claims 1-6, as written, fail to satisfy the written description requirement.

Moreover, claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, for failing to satisfy the written description requirement, because the instant claims are directed to a bioemulsifier comprising 50.5% protein, 43% polysaccharide and 3.8% lipid, where the components of the claimed product are not defined, except by a functional characteristic (i.e., the claimed composition has emulsifying properties). The Court of Appeals for the Federal Circuit has recently held that a written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials. See *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original).

Just as the claims at issue in *UC v. Lilly* defined the invention by the function of the claimed DNA (encoding insulin), the instant claims define the claimed product only by its functional property. The court held this sort of functional definition insufficient. In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly such a formula is normally an adequate description of the claimed genus.

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In claims to biological material, such as genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is (see *UC v. Lilly*, at \*24-\*25). In the instant case, claim 1 recites a protein, polysaccharide and lipid mixture that is an emulsifier. Consequently, the instant claims are not adequately defined by the specification in this case for the same reasons that the claims in *UC v. Lilly* were found to be inadequately defined.

Claim 1-6 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a bioemulsifier composition from *Acinetobacter junii* SC14 (NCIM 5150) comprising 50.5% protein, 43% polysaccharide and 3.8% lipid does not reasonably provide enablement for a bioemulsifier composition from any source or sources comprising 50.5% protein, 43% polysaccharide and 3.8% lipid (claim 1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This claim language encompasses a

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multitude of possible proteins, polysaccharides and lipids, including molecules neither contemplated nor disclosed by the specification as filed and for which Applicants have provided no guidance as to their identification or structure, or as to methods for their selection or isolation. In view of the great extent of the claimed subject matter, combined with the fact that the specification as filed provides a description of only a limited amount of guidance (bioemulsifier from *Acinetobacter junii* SC14 (NCIM 5150), it is clear that in order to practice the scope of the claimed subject matter, the artisan of ordinary skill would have expected to have undertaken essentially a trial and error process. Such a process clearly amounts to undue experimentation. Because the specification provides no guidance as to the bioemulsifier to be made and the methods by which such a bioemulsifier would be made, the skilled artisan clearly would have expected to have to experiment unduly to practice the claimed invention. In sum, undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary (immense because the protein, polysaccharide and lipid components are undefined, apart from the functional limitation that the protein is an esterase); limited amount of guidance and limited number of working examples in the specification (only bioemulsifier from *Acinetobacter junii* SC14 (NCIM 5150) is disclosed); nature of the invention (only one bioemulsifier has been invented); state of the prior art (bioemulsifiers from other microorganisms, such as other *Acinetobacter* are known but not completely biochemically characterized); relative skill level of those in the art; predictability or unpredictability in the art (no predictability because the behavior of undefined materials is inherently unpredictable); and breadth the claims (discussed

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above) (In re: Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). Claims 1-6, therefore, fail to satisfy the enablement requirement.

Biological deposit required

The invention appears to employ a novel microorganism. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed microorganism, isolated from a human, and the method of isolation are not fully disclosed, nor is the source of the organism publicly known and freely available. The specification does not disclose a repeatable process to obtain the microorganism, and it is not apparent if the microorganism is readily available to the public. The enablement requirements of 35 USC §112 may be satisfied by a deposit of the microorganism. Accordingly, it is deemed that a deposit of this microorganism should have been made in accordance with 37 C.F.R. 1.801-1.809.

If a deposit has been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition be released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicants

may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever become inviable.

Additionally, amendment of the specification to recite the date of the deposit, the complete name and address of the depository, and the accession number of the deposited cell line is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors, rendering the claims confusing and the meaning of the claims unclear. For example, claim 1 recites a bioemulsifier comprising of protein content 50.5%, polysaccharide 43% and lipid content 3.8%." Applicants may wish to amend this claim to recite a bioemulsifier composition

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comprising the appropriate amount of protein, the appropriate amount of polysaccharide and the appropriate amount of lipid. Applicants should note that the claimed percentages add up to only 97.3%. The remainder of the composition is not indicated. Applicants should also note that the claim does not provide for variability in the preparation of the bioemulsifier from these ingredients. If percentages are used, Applicants should also indicate whether these percentages are by weight, on a molar basis, or based on something else. Claim 2 recites that "the bioemulsifier showed peak esterase activity cell associated of order of 61.3% and 38.6% activity was secreted ...". If appropriate, Applicants may wish to amend the claim to recite that 61.3% of the esterase, as measured by enzyme activity, is associated with the cells and 38.6% of the esterase is secreted into the fermentation medium. Additionally, Applicants should note that claims 2-6 fail to limit further the composition of claim 1, as they recite characteristics or location of the composition without changing the composition itself. A holding of indefiniteness is therefore required.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

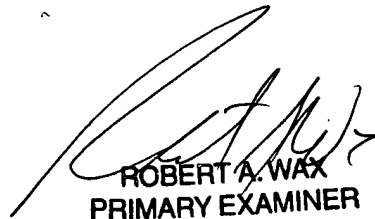
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson  
Examiner  
Art Unit 1651

rk  
2005-02-02

  
ROBERT A. WAX  
PRIMARY EXAMINER  
Art Unit 1653